

a1  
pharmaceutically effective amount of] microparticles sized such that at least 50% of the microparticles are less than 5  $\mu$ m, the microparticles comprising the at least one antigen entrapped or encapsulated by [a] the biodegradable polymer; and  
combining a pharmaceutically effective amount of said microparticles with a pharmaceutically acceptable carrier to provide said vaccine formulation for oral administration.

Claim 2, line 1, change "vaccine formulation" to --method--.

a2  
3. (Amended) The [vaccine formulation] method of Claim 1, wherein the biodegradable polymer comprises a copolymer of lactic acid or an enantiomer of lactic acid with [and] glycolic acid or [enantiomers thereof] an enantiomer of glycolic acid.

Claim 5, line 1, change "vaccine formulation" to --method--.

Claim 6, line 1, change "vaccine formulation" to --method--.

a3  
7. (Amended) A method for producing a vaccine formulation for oral administration, said method comprising:

coacervating at least one antigen with a biodegradable polymer to provide [a pharmaceutically acceptable carrier and a pharmaceutically effective amount of] nanoparticles sized such that at least 50% of the nanoparticles are less than 600nm, the nanoparticles comprising the at least one

a3  
antigen entrapped or encapsulated by [a] the  
biodegradable polymer; and  
combining a pharmaceutically effective amount of said  
nanoparticles with a pharmaceutically acceptable carrier  
to provide said vaccine formulation for oral  
administration.

Claim 8, line 1, change "vaccine formulation" to --method--.

a4  
9. The [vaccine formulation] method of Claim 7, wherein the  
biodegradable polymer comprises a copolymer of lactic acid or an  
enantiomer of lactic acid with [and] glycolic acid or [enantiomers  
thereof] an enantiomer of glycolic acid.

Claim 11, line 1, change "vaccine formulation" to --method--.

Claim 12, line 1, change "vaccine formulation" to --method--.

a5  
13. (Amended) A method of inducing a protective immune  
response against *B. pertussis*, comprising orally administering to  
a subject a pharmaceutically effective amount of microparticles  
sized such that at least 50% of the microparticles are less than 5  
µm, the microparticles comprising at least one *B. pertussis* antigen  
selected from the group consisting of inactivated pertussis toxin  
(PTd), filamentous hemagglutinin (FHA) and pertactin, entrapped or  
encapsulated by a biodegradable polymer.

a6  
15. (Amended) The method of Claim 13, wherein the  
biodegradable polymer comprises a copolymer of lactic acid or an

enantiomer of lactic acid with [and] glycolic acid or [and enantiomers thereof] or an enantiomer of glycolic acid and wherein the microparticles are formed using a solvent evaporation method.

ab 16. (Amended) The method of Claim 13, wherein the at least one *B. pertussis* antigen [is selected from the group consisting of] comprises inactivated pertussis toxin (PTd)[,] and filamentous hemagglutinin (FHA)[, pertactin and fimbriae and combinations thereof].

17. (Amended) A method of inducing a protective immune response against *B. pertussis*, comprising orally administering to a subject a pharmaceutically effective amount of nanoparticles sized such that at least 50% of the nanoparticles are less than 600nm, the nanoparticles comprising at least one *B. pertussis* antigen selected from the group consisting of inactivated pertussis toxin (PTd), filamentous hemagglutinin (FHA) and pertactin, entrapped or encapsulated by a biodegradable polymer.

an 19. (Amended) The method of Claim 17, wherein the biodegradable polymer comprises a copolymer of lactic acid or an enantiomer of lactic acid with [and] glycolic acid or [enantiomers thereof] an enantiomer of glycolic acid and wherein the nanoparticles are formed using a coacervation method.

20. (Amended) The method of Claim 17, wherein the at least one *B. pertussis* antigen [is selected from the group consisting of]